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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/560,288	04/27/2000	Edward Nathaniel Hanley JR.	8151-24A	3083

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EXAMINER	
HAYES, ROBERT CLINTON	

ART UNIT	PAPER NUMBER
1647	22

DATE MAILED: 10/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/560,288	Applicant(s) Hanley et al
	Examiner Robert C. Hayes, Ph.D.	Art Unit 1647

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jun 18, 2003* .

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *35 and 37-58* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *35 and 37-58* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Response to Amendment

1. The amendment filed 6/18/03 has been entered. It is noted that no interference can be declared until claims are allowable.

2. The Katz Declaration under 37 CFR 1.132 filed 6/18/03 is sufficient to overcome the rejection of claims 35-38 as rejected under 35 U.S.C. 102(a) as being anticipated by Gruber et al. (1997; IDS Ref #26), or by Gruber et al. (Matrix Biology 16: 285-288 (1997)).

3. Applicant's arguments filed 6/18/03 have been fully considered but they are not deemed to be persuasive.

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 35 & 37-38 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

No proper antecedent basis nor conception in context with that described within the specification at the time of filing the instant invention is apparent for treating human disc diseases using "a carrier *in the form of a hydrogel... forming a three-dimensional carrier*" (i.e., as it relates to claim 35). In contrast, page 9 of the specification describes use of an "injectable hydrogel... without invasive surgical procedures"; thereby, not reasonably "forming a three-dimensional carrier" before implantation, as claimed, and therefore, constituting new matter.

6. Claims 35, 37-51 & 53-58 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for using therapeutic compositions comprising "early childhood" human intervertebral disc cells and a carrier that contain required and defined cell stimulants/growth factors/carrier molecules to aid in the treatment of human disc diseases or injuries, does not reasonably provide enablement for uses of such cells from adolescents or adults wherein annulus and/or nucleus cells no longer exist, or for compositions missing required/ defined components or comprising carrier derivatives thereof (i.e., in that none of the claims recite each and every required component, and instead claim piecemeal recitations). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims, for the reasons made of record in Paper Nos: 3 (mailed 9/13/00), 7 (mailed 5/09/01) and 16 (mailed 5/21/02) for old claims 35-38, etc.

It is noted that Applicants' arguments on pages 6-7 of the response, as it relates to the claims now being "revised... to a 'method' " fails to address the issues raised in the previous Office actions. Additionally, the Declaration filed 7/26/01 fails to address the issues for these new claims. It is noted that Declarant's "opinion" that the results of the "sand rat" model is "translatable to human" is not fully persuasive for methods of treatment, because the "sand rat" is a quadruped that would not reasonably experience the shock absorber function/stress/mechanical loading requirements of the disc in the larger biped human, in order to provide a reasonable enabling treatment, based on the teachings of Aigner et al. (1997), Guilak et al. (1999), Frick et al. (1994) and Luk et al (1997) previously made of record.

Lastly, as previously made of record, the metes and bounds of what cell stimulants/ "growth factors or cytokines", and carrier "derivatives" thereof in new claims 43, 50 & 58, are required to proliferate the "cultured disc tissue", etc. are not adequately defined in the specification, nor specifically defined in the claims; thereby, preventing the skilled artisan from knowing how to determine how to make and use these "cultured disc tissue" without requiring undue experimentation to determine such (i.e., as it relates to claims 43-44, 50-51, 55 & 58).

7. Claims 37-52, 54 & 58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is confusing why it is important to "treat... a diseased or injured invertebral (*sic*) disc *having nucleus and annulus regions*", when the disease or injury (or even normal development) may have destroyed these two regions which are normally present in healthy early childhood tissue (i.e., as it relates to claim 39). It is further confusing why one would "mince" "intervertebral cells", versus "disc tissue" as disclosed on page 5 of the specification (i.e., as it relates to claims 41 & 54).

Second, no antecedent basis exists in claims 37 & 38 for the recitation of "therapeutic composition" in base claim 35, which is now directed to "a method". No antecedent basis exists for the recitation of "said *cultured* disc tissue" in claims 39 & 52, or for "said *cultured human intervertebral* disc tissue" (i.e., as it relates to claims 42 & 49) and the recitation of "obtain an explant" in base claim 39 (i.e., as it relates to claims 41, 45, 47 & 51). No antecedent basis further exists for the recitations of "said isolated disc tissue" or "said distributed tissue" in claim 47.

8. Claims 35, 37-38 & 47-51 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: "debriding the diseased or injured disc tissue" in order to have room to implant a "three dimensional structure", as required in claims 35 & 47.

It is noted that Applicants are attempting to alter a previous product-by-process claim into a treatment claim, which contains limitations that do not readily flow into a method of treatment, as currently claimed (i.e., as it relates especially to claims 35 & 47).

9. Claims 52-58 are rejected under 35 U.S.C. 102(a) as being anticipated by Chelberg et al (J. Anat. 186: 43-53 (1995)), for the reasons made of record in Paper No: 3 (mailed 9/13/00) & 16 (mailed 5/21/02) for old claims 35-38, and as follows.

It is noted that Applicants' arguments on pages 7-8 of the response, as it relates to "in view of the amendments to the Claim 35" fail to address the issues raised in the previous Office actions, as it relates to these product claims and method of producing such, which Chelberg et al. reasonably teach for the reasons previously made of record.

The issue again then becomes that if the product in a product-by-process claim (i.e., a "cultured disc tissue" comprising a carrier material and *in vitro* "live" human intervertebral cells) is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior art product was made by a different process. *In re Thorpe.*, 227 USPQ 964, 966 (Fed. Cir. 1985): *In re Marosi*, 218 USPQ 289, 292-293 (Fed. Cir. 1983).

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (703) 305-3132. The examiner can normally be reached on Monday through Thursday, and alternate Fridays from 8:30 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623. The fax phone number for this Group is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Robert C. Hayes, Ph.D.
October 10, 2003

LORRAINE SPECTOR
PRIMARY EXAMINER